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A cardiac stimulating device

BACKGROUND OF THE INVENTION

1. Field of the invention

The present invention relates to an implantable cardiac stimulating device according to the preamble of the attached independent claim. More precisely, the invention concerns a biventricular pacemaker capable of monitoring capture on the implanted ventricular electrodes. The invention is also applicable for an Implantable Cardioverter Defibrillator, ICD, comprising a biventricular pacemaker.

2. Description of prior art

Most pacers are arranged to stimulate the right ventricle of the heart but it is also known to stimulate the left ventricle. In particular, for treatment of congestive heart failure combined with ventricular dyssynchrony, it is known to stimulate both ventricles, in order to optimize the hemodynamic performance of the heart.
The improvement in hemodynamic performance that can be obtained is due to improved synchronization between the right and left ventricles. If capture is lost on any of the two ventricular stimulating electrodes the beneficial effect of the biventricular pacing therapy is lost.

US 5,740,811 discloses a device and method to synthesize an ECG which in appearance can be substituted for a surface ECG. The synthesized ECG is based on endocardial signals obtained from pacemaker heart electrode leads.

US patent application US 2001/0049542 A1 discloses a biventricular pacemaker in which a bichamber composite

cardiac signal is analysed to determine if biventricular capture is present.

US 6,148,234 discloses a biventricular pacing system adapted to determine capture or not on both ventricular chambers. Loss of capture on one chamber is determined if an R-wave is detected in that particular chamber during a refractory period after the stimulation pulses.

US patent application US 2001/0049543 A1 discloses a biventricular pacemaker utilizing a crosschamber stimulation method. Biventricular capture can be determined in a cross chamber sensing configuration preferably in a ring to ring electrode configuration.

WO 01/74441 discloses an apparatus and method for verifying capture by a selected electrode in a multisite pacemaker. A switching circuit switches the input of an evoked response channel to an unselected electrode. Presence or absence of capture is determined from the output of the evoked response sensing channel.

WO 99/29368 discloses an implantable device that automatically verifies capture. During predetermined periods, the device utilizes two or more pacing/sensing electrodes positioned within an electrically continuous area of the heart, wherein one electrode is used to provide a pacing stimulus and the other electrodes are used to determine capture.

An Abstract in Pace "ECG characteristics of simultaneous Biventricular Stimulation in Canines" by Rick McVenes and Melissa Christie discloses that biventricular capture gives shorter QRS and QT durations and that the paced QRS axis is affected depending on if there is single site or dual site biventricular capture. The abstract was published in PACE, Vol. 21, April 1998, Part II, page 893.

A problem with prior art biventricular pacemakers equipped with features to assure capture after stimulation pulses is that it is difficult to verify capture on every beat particularly if the pacemaker can work with a delay between the stimulation of the first ventricle and the second ventricle. The reason is that the stimulation pulse to the second ventricle may make it impossible to detect capture from the stimulation pulse delivered to the first ventricle. After a delivered stimulation pulse the evoked response detection window typically ends 50-100 ms after the stimulation and a second stimulation pulse delivered during this period will make it difficult to detect the evoked response from the first stimulation pulse.

One object of the present invention is to achieve an improved biventricular pacemaker adapted to verify capture on both ventricles for every cardiac cycle. Thus it will be possible to make the necessary adjustment of the pacing pulse energy to obtain biventricular capture from one pacing cycle to the next.

SUMMARY OF THE INVENTION

The object of the invention is obtained by an implantable cardiac stimulating device as defined in the opening paragraph of the description having the characterizing features of claim 1.

The invention utilizes the fact that, as indicated above, loss on the right or on the left ventricle can easily be determined through a relatively uncomplicated analysis of a surface ECG. If there is a loss on one of the two stimulating electrodes there will be a significant change in the surface ECG morphology.

In this invention an intracorporal ECG signal obtained from a location inside the body but outside of the heart is used instead of a regular surface ECG. A normal ECG signal represents the electrical activity of the heart observed at

a location on the body surface. The most significant factor that controls the morphology of an ECG is the direction and distance to the heart. An intracorporal ECG signal may be relatively similar to a surface ECG signal if the direction and distance to the heart are similar.

According to a first embodiment of the invention the intracorporal ECG is sensed at measuring points outside of the heart but inside the body after delivery of a biventricular stimulation. At least one characteristic of the evoked intracorporal QRS is analyzed to determine if biventricular capture is present. Possible characteristics for the analysis are e.g. QRS duration or QRS morphology.

According to a further embodiment the intracorporal ECG is sensed between a measuring point located on the connector top and the pulse generator encapsulation.

According to a further embodiment the intracorporal ECG is sensed between a short nonendocardial electrode lead and the pulse-generator encapsulation.

According to a further embodiment the intracorporal ECG is measured between a ring electrode located outside the heart on one of the endocardial heart electrode leads and the pulse generator encapsulation.

According to a further embodiment multichannel intracorporal sensing is performed between a short nonendocardial electrode lead, one or more endocardial ring electrodes and the pulse generator encapsulation.

According to a further embodiment a back-up pulse is delivered to at least one of the ventricular electrodes if the intracorporal ECG does not indicate an evoked R-wave.

According to a further embodiment the disclosed intracorporal ECG analyzing means is incorporated in an Implantable Cardioverter Defibrillator, ICD.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1 shows schematically a prior art implanted biventricular pacemaker system.

Fig 2 shows schematically an implanted biventricular pacemaker system with intracorporal ECG monitoring through a short intracorporal nonendocardial ECG monitoring electrode lead.

Fig 3 shows schematically an implanted biventricular pacemaker system with intracorporal ECG monitoring through an electrode dot located on the implanted pulse generator.

Fig 4 shows schematically an implanted biventricular pacemaker system with intracorporal ECG monitoring through ring electrodes placed on the endocardial heart electrode leads.

Fig 5 shows a schematic drawing of a control circuit in an implantable medical device according to the invention.

Fig 6 shows examples of a typical surface ECG:s for right ventricular pacing, left ventricular pacing and biventricular pacing respectively.

Fig 7 shows an example of a typical ECG with right atrial stimulation and biventricular stimulation with one example of left ventricular loss.

Fig 8 shows a detailed block diagram of intracorporal ECG analyzing means 23.

DESCRIPTION OF PREFERRED EMBODIMENTS

Fig 1 shows a prior art biventricular pacemaker system as implanted. In this example an atrial heart electrode lead 1 is provided for atrial sensing/pacing by the implanted pulse generator 2. Further a left ventricular heart electrode lead 3 is provided for left ventricular sensing/pacing. The heart electrode lead 3 is implanted via the coronary sinus vein to a preferred position epicardially on the left ventricle. For right ventricular sensing/pacing a conventional right ventricular heart electrode lead 4 is provided. In some embodiments a fourth (not shown) left atrial heart electrode lead is provided for left atrial sensing/pacing.

Fig 2 shows a biventricular pacemaker according to the invention as implanted. A short nonendocardial electrode lead 6 is provided for sensing an intracorporal ECG from a position outside of the heart. In the figure it is assumed that the intracorporal ECG is sensed between the pulse generator 5 encapsulation and the short nonendocardial electrode lead 6. There may be several short nonendocardial electrode leads to provide several different intracorporal ECG sensing configurations. In the absence of intrinsic atrial event signals pacing pulses are delivered to the atrial heart electrode lead 1. Following an atrial sensed/paced event an AV interval is initiated. At the end of the AV interval pacing pulses are delivered to the right ventricular heart electrode lead 4 and to the left ventricular heart electrode lead 3. Following the delivery of the ventricular pacing pulses an evoked intracorporal QRS is sensed via the short nonendocardial electrode lead 6 and the pulse generator 5 encapsulation. The implanted pulse

generator 5 performs an analysis of the evoked intracorporal QRS to determine if biventricular capture is present or if there is loss on one or both of the ventricular heart electrode leads (3,4). Criteria to determine capture or not may be evoked QRS duration or morphological criterias such as surface under the positive and negative deflection of the evoked QRS or the order in which negative and positive deflections occur or the duration of the most significant deflection in the evoked intracorporal ECG signal. An intracorporal ECG configuration similar to configuration V1 or CR1 in a surface ECG is an advantageous configuration even though any configuration can be used with appropriate adaptation of the analysis of the intracorporal ECG signal. Surface ECG configuration CR1 is recorded from a measuring point located in the middle of the chest with the right arm as indifferent while V1 uses the same measuring point but the indifferent is from a point that is connected via three identical resistors connected to the left arm, right arm and the left leg. It is of course not possible to achieve exactly the same measurement configuration in an intracorporal ECG as in a surface ECG. Generally an intracorporal ECG configuration that provides a good visibility of the electrical activity of both ventricles is favorable. In V1 or CR1 the electrical activity of both ventricles are clearly visible and therefore a loss of capture in any of the left or right ventricles can easily be detected in V1 or CR1 by analyzing the evoked electrical activity from the pacing pulses.

Fig 3 shows a biventricular pacemaker according to the invention. An intracorporal ECG sensing electrode dot 7 is placed on the connector top of the pulse generator 8 and the intracorporal ECG is sensed between the electrode dot 7 and the encapsulation of the pulse generator 8. This configuration will provide a relatively short distance of a few cm between the electrode dot 7 and the pulse generator encapsulation, which serves as indifferent. This will result in a lower signal amplitude but this can be compensated by a

higher amplification of the signal picked up. In order to obtain several configurations of the intracorporal ECG several electrode dots can be placed on the encapsulation and on the connector top of the pulse generator 8. Regarding the function of the pulse generator 8 the description for fig 2 is applicable also for fig 3.

Fig 4 shows a biventricular pacemaker according to the invention. One or more of the endccardial heart electrode leads 1,3,4 is provided with ring electrodes such as 9,10 to be placed outside the heart for sensing an intracorporal ECG. A particularly advantageous method to connect the ring electrodes 9,10 to the control unit of the pulse generator (11) may be to use a proposed electrode lead connector standard, IS-4, which may provide 4 individual contacts for each IS-4 connector. The intracorporal surface ECG can be obtained between the pulse generator 11 encapsulation and any of the ring electrodes 9,10 or between the ring electrodes 9,10. This will provide several configurations for intracorporal ECG sensing.

Fig 5 shows a block diagram of a control circuit 34 used in the pulse generator 2,5,8 and 11. The control circuit comprises pacing pulse output circuits 12, 13, 14, 15 for delivering stimulation pulses to heart electrode leads 1, 3, 4. The control circuit 34 is adapted for a general pacing system configuration where right and left atria as well as right and left ventricles are paced and sensed. However in many cases the pacing system comprises one atrial heart electrode lead and two ventricular heart electrode leads. The control circuit 34 further comprises sense amplifiers and detectors 16, 17, 18, 19 for sensing atrial and ventricular activity respectively. Sense amplifiers 20 and 21 are used for sensing an intracorporal ECG signal from locations outside of the heart. The control circuit 34 also comprises means 22 arranged to enable the delivery of stimulating pulses to the first and second 3, 4 ventricular

heart electrode leads within the same heartcycle such that there may be a time interval dT between the stimulating pulses. The time interval dT may be varied.

Furthermore the control circuit 34 in the present invention comprises means 23 for analyzing the intracorporal ECG signal obtained via sense amplifiers 20 and 21. The analysis may include QRS duration, QRS morphology, duration of most significant deflection, or ST segment visibility. From the analysis it can be determined if there is capture on both ventricles via heart electrode leads 3 and 4 or if there is loss on one or both of the ventricles. If there is loss on both ventricles no intracorporal evoked QRS will be present and a back-up pacing pulse to one or both ventricles will be emitted by pacing pulse output circuits 14, 15.

Fig 6 shows samples of surface ECG (V1) obtained during pacing. Complex 24 is obtained during right ventricular pacing (RV pacing), complex 25 is obtained during left ventricular pacing (LV pacing), while complex 26 is obtained during biventricular simultaneous right and left ventricular stimulation. As can be seen in surface ECG configuration V1 the order of deflections are opposite when comparing LV and RV pacing.

It is thus possible to determine if there is left ventricular loss of capture which will give an intracorporal ECG similar to complex 24 in fig 6 which is obtained during right ventricular pacing. Similarly an intracorporal ECG similar to complex 25 in fig 6 indicates right ventricular loss of capture. Biventricular capture yields a surface ECG similar to complex 26 in fig 6. As can be seen the QRS duration is significantly shorter compared to left or right ventricular pacing when biventricular capture is present. Further the order of deflections is reversed when comparing left and right capture. A morphology analysis of the intracorporal ECG may be adapted to indicate loss of capture on any ventricular heart electrode lead and further determine if the loss was on the left or right ventricular heart electrode lead. Other ECG configurations can also be

employed for analyzing evoked QRS characteristics that indicate capture of the right or left or both ventricles. When biventricular pacing is applied the QRS is significantly shortened, the QRS has a unique morphology, and there is a visible S-T segment.

An intracorporal ECG obtained from a location just under the skin is similar to a surface ECG obtained from a similar location on the surface of the skin. The surface ECG shows a greater variability due to polarization and contact problems with the ECG electrodes. This problem is not present with electrodes located under the skin for intracorporal sensing of the ECG signal. Thus an intracorporal ECG signal shows a better stability compared to a normal surface ECG signal. Some of the proposed intracorporal ECG configurations use sensing electrode locations that are deeper into the body than subcutaneous which will cause some variation of the signal morphology of the intracorporal ECG compared to a normal surface ECG. However it is always the distance and direction to the heart that determines the potential that an ECG sensing electrode will see regardless of if it is located inside of the body or on the body surface. Once the intracorporal sensing electrodes are placed the obtained signal morphology from the implanted intracorporal electrodes may be analyzed to determine criteria to be used for determination of biventricular capture, left ventricular loss or right ventricular loss.

Fig 7 shows a schematic ECG indicating the function of a biventricular pacemaker utilizing the invention. In the first complex 27 an atrial stimulation pulse is indicated followed by biventricular stimulation pulses which are followed by the evoked QRS. The evoked QRS showed is obtained from surface ECG lead V1 but a similar signal can be obtained through electrode leads implanted under the skin at a location close to the corresponding surface ECG lead.

The evoked QRS is analyzed by means 23 in the control circuit. In complex 27 there is biventricular capture and no

change of stimulation amplitude is required. In complex 28 the morphology indicates that there is a loss of capture on the left ventricular electrode lead since the complex morphology is similar that of right ventricular pacing. In the following cycle the pacemaker may just increase the output amplitude on the left ventricular output to accommodate for any threshold change. Another possibility is to execute a full threshold search procedure because of the changed threshold.

Fig 8 shows a block diagram for analyzing means 23 for analyzing the intracorporal ECG signal. The incoming intracorporal ECG signal is A/D converted by A/D converter 36. Reference signals representing biventricular capture; right ventricular capture or left ventricular capture are stored in reference memory 37. The data stored in reference memory 37 may be obtained as an average of several heart complexes in order to improve noise suppression. The updating of the reference memory may either be manual under physician control or automatically controlled by the pulse generator itself. For each stimulated beat the evoked intracorporal ECG signal is compared by comparison means 38 with a reference signal representing biventricular capture, right ventricular capture, left ventricular capture. The comparison means may for example calculate the sum of the squared difference between the reference and the actual signal for each sample of the signal. The reference signal that gives lowest squared sum is judged to be of the same type as the actual signal. After determination of in which heart chamber the loss has occurred the amplitude of the pacing pulses can be adjusted accordingly. This method is relatively computationally intensive and it may be feasible to use this method only at certain occasions. An alternative method may be to measure the QRS duration of the evoked intracorporal ECG. Means 39 may for example comprise a timer which starts when the intracorporal QRS deviates by a certain amount from the baseline and stops when the

intracorporal QRS has returned to a value close to the baseline. The interval recorded by such a timer comprised by QRS duration means will represent the duration of the intracorporal QRS. A prolonged intracorporal QRS duration indicates that biventricular capture is lost. In response to this observation the controller may initiate a morphology comparison in order to find out if there was loss on the right or left ventricle. Alternatively the pacing amplitudes to the right and left ventricles may be adjusted in an iterative search process until the duration of the evoked intracorporal QRS has reached the normal duration. Another possibility would be to analyze the sequence of positive and negative peaks in the intracorporal ECG to determine if biventricular, right ventricular or left ventricular capture is present. Means 40 comprised in the analyzing means 23 records for every stimulated beat the sequence of positive and negative peaks in the intracorporal QRS. The reference memory (37) contains the sequence of positive and negative peaks for biventricular and right and left ventricular capture. The reference memory 37 is updated to contain representative sequences in the same fashion as described above. The comparison means 38 can then for each stimulated heart beat determine if there was biventricular capture or if there was right or left ventricular capture. This determination will allow the control circuit 34 to change the stimulation amplitude on the right or left ventricular channel if necessary to maintain biventricular captures. Another possibility would be to analyze the sequence of positive and negative slopes in the intracorporal QRS to determine if biventricular, right ventricular or left ventricular capture is present. Means 41 comprised in the analyzing means 23 records for every stimulated beat the sequence of positive and negative slopes in the intracorporal QRS. The reference memory contains the sequence of positive and negative slopes for biventricular and right and left capture. The reference memory 37 is updated to contain representative sequences is the same

fashion as described above. The comparison means 38 can then for each stimulated heart beat cetermine if there was biventricular capture or if there was right or left ventricular capture. This determination will allow the controller 23 to change the stimulation amplitude on the right or left ventricular channel if necessary to maintain biventricular capture.

List of reference numerals

1	Atrial heart electrode lead
3	Left ventricular heart electrode lead
4	right ventricular heart electrode lead
2,5,8,11	Pulse generator
6	Short nonendocardial electrode lead
7	Electrode dot
9,10	Ring electrode
12,13,14,15	Pacing pulse output circuit
16,17,18,19	Sense amplifier and detector
20,21	Sense Amplifier
22	means for delivering pacepulses with an interval dT between stim pulses
23	means for analyzing the intracorporal ECG
24	right ventricular pacing complex
25	Left ventricular pacing complex
26	Biventricular pacing complex
27	Complex indicating biventricular capture
28	Complex indicating right ventricular capture
34	control circuit
36	A/D converter
37	Reference memory
38	Comparison means
39	QRS duration recording means
40	QRS sequence of peaks recording means
41	QRS sequence of slopes recording means

Claims

1. An implantable biventricular cardiac stimulating pulse generator (2,5,8,11) comprising:

a housing,

a control circuit (34) enclosed in said housing, said control circuit (34) having first connecting means being connectable to a first heart electrode lead (3) to be positioned to stimulate a first ventricle of a heart,

said control circuit also having second connecting means being connectable to a second heart electrode lead (4) to be positioned to stimulate a second ventricle of said heart, said control circuit (34) also having a third connecting means being connectable to at least one electrode(6, 7, 9, 10) located at a distance from the heart for sensing an intracorporal ECG,

said control circuit comprising means (20, 21) arranged for sensing at least one intracorporal ECG signal after stimulating said first and second ventricles respectively,

said control circuit (34) comprising means (14, 15) for delivering stimulation pulses to said first (3) and second (4) heart electrode leads in order to stimulate said first and second ventricles respectively,

characterized in that the control circuit (34) comprises means (23) adapted to analyze at least one characteristics in said intracorporal ECG, said characteristics providing information on whether a loss of capture has occurred on any or both of said ventricular heart electrode leads.

2. An implantable heart stimulator according to claim 1 characterized in that said means 23 is adapted to determine on which heart electrode a loss has occurred.

3. An implantable heart stimulator according to claim 2 characterized in that said control circuit (34)

comprises means to adjust the pacing pulse amplitude to eliminate a loss of capture situation.

4. An implantable cardiac stimulating device according to claim 1 characterized in that said characteristics in said intracorporal ECG is the QRS duration.

5. An implantable cardiac stimulating device according to claim 1 characterized in that said characteristics in the intracorporal ECG is the QRS morphology.

6. An implantable cardiac stimulating device according to claim 5 characterized in that said QRS morphology is analyzed by comparison means (38) to determine if said QRS morphology indicates biventricular capture, right ventricular capture or left ventricular capture.

7. An implantable cardiac stimulating device according to clam 1 characterized in that said characteristics in the intracorporal ECG is the sequence of positive and negative peaks in the intracorporal ECG.

8. An implantable cardiac stimulating device according claim 1 characterized in that said characteristics in the intracorporal ECG signal is the sequence of positive and negative slopes in the intracorporal ECG.

9. An implantable cardiac stimulating device according to claim 1 characterized in that said characteristics in the intracorporal ECG is the presence or absence of a visible ST segment.

10. An implantable cardiac stimulating device according to any of the preceding claims characterized in that the pulse generator (2,5,8,11) encapsulation is used as an electrode for sensing said intracorporal ECG.

11. An implantable cardiac stimulating device according to claim 1-3 characterized in that at least one short nonendocardial electrode lead (6) is used for sensing said intracorporal ECG.

12. An implantable cardiac stimulating device according to claim 1 characterized in that at least one electrode dot (7) is located on the implantable heart stimulator encapsulation for sensing said intracorporal ECG.

13. An implantable cardiac stimulating device according to claim 1-3 characterized in that at least one ring electrode (9, 10) located on one endocardial electrode lead is utilized for sensing said intracorporal ECG.

14. An implantable cardiac stimulating device according to claim 1 characterized in that a back-up pulse is delivered to at least one ventricle if said intracorporal ECG indicates a complete loss of capture.

Abstract

The invention concerns a cardiac stimulating device for biventricular stimulation. An intracorporal ECG signal obtained from measuring electrode leads located outside of the heart is used for monitoring capture of the right and left ventricles. If loss of capture is detected on any of the ventricles then the pacing pulse energy will be adjusted to obtain complete biventricular capture.
(fig 2)

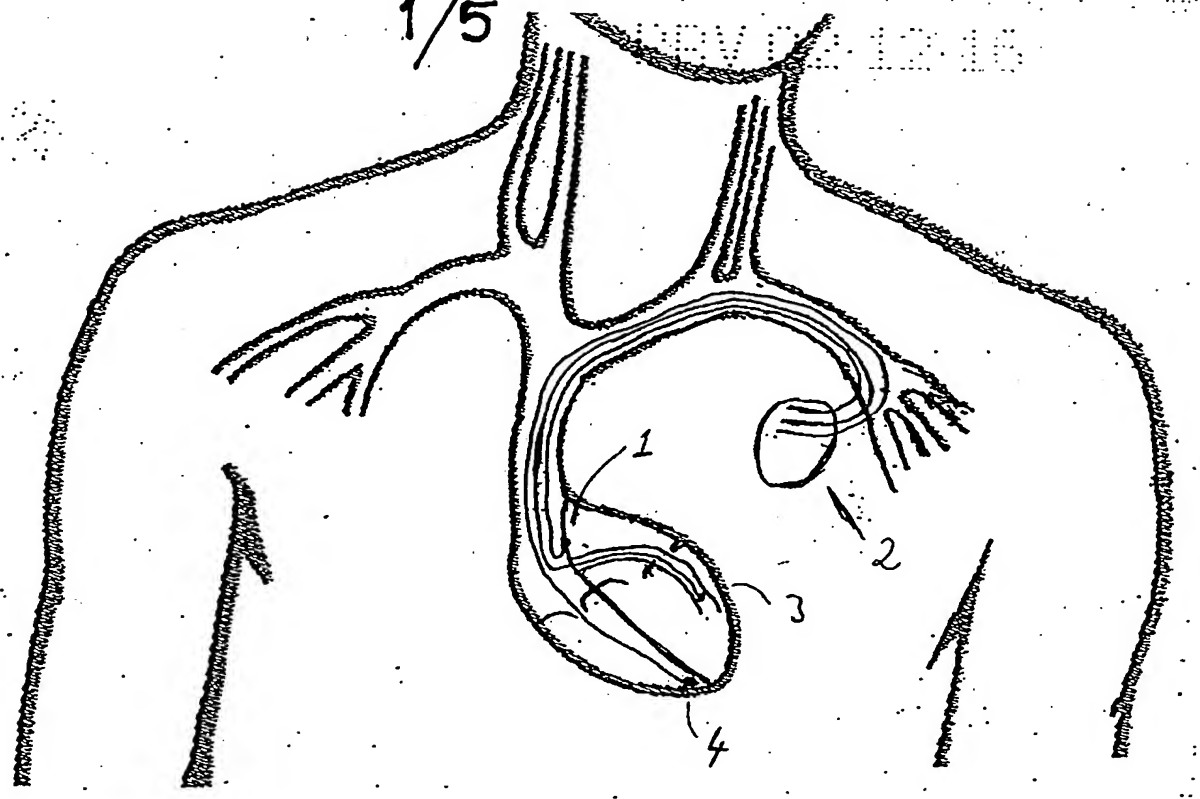

Fig 1

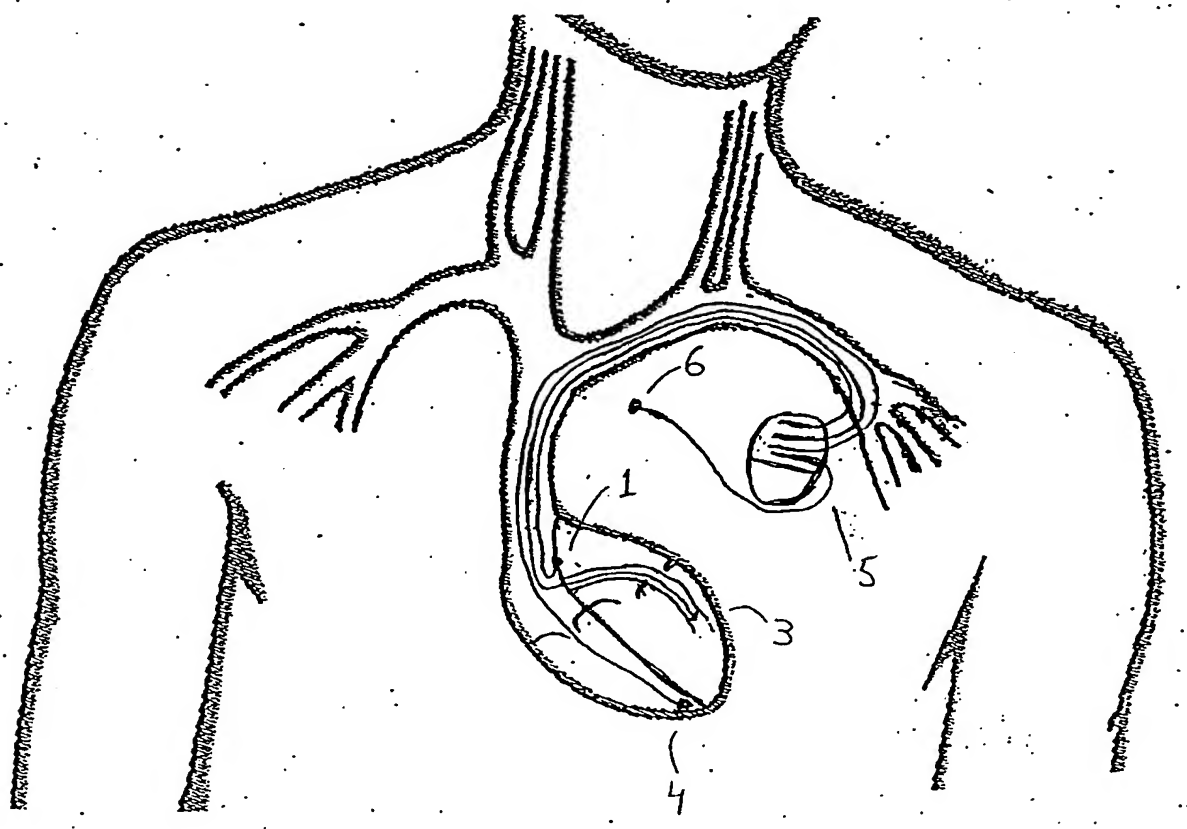

Fig 2

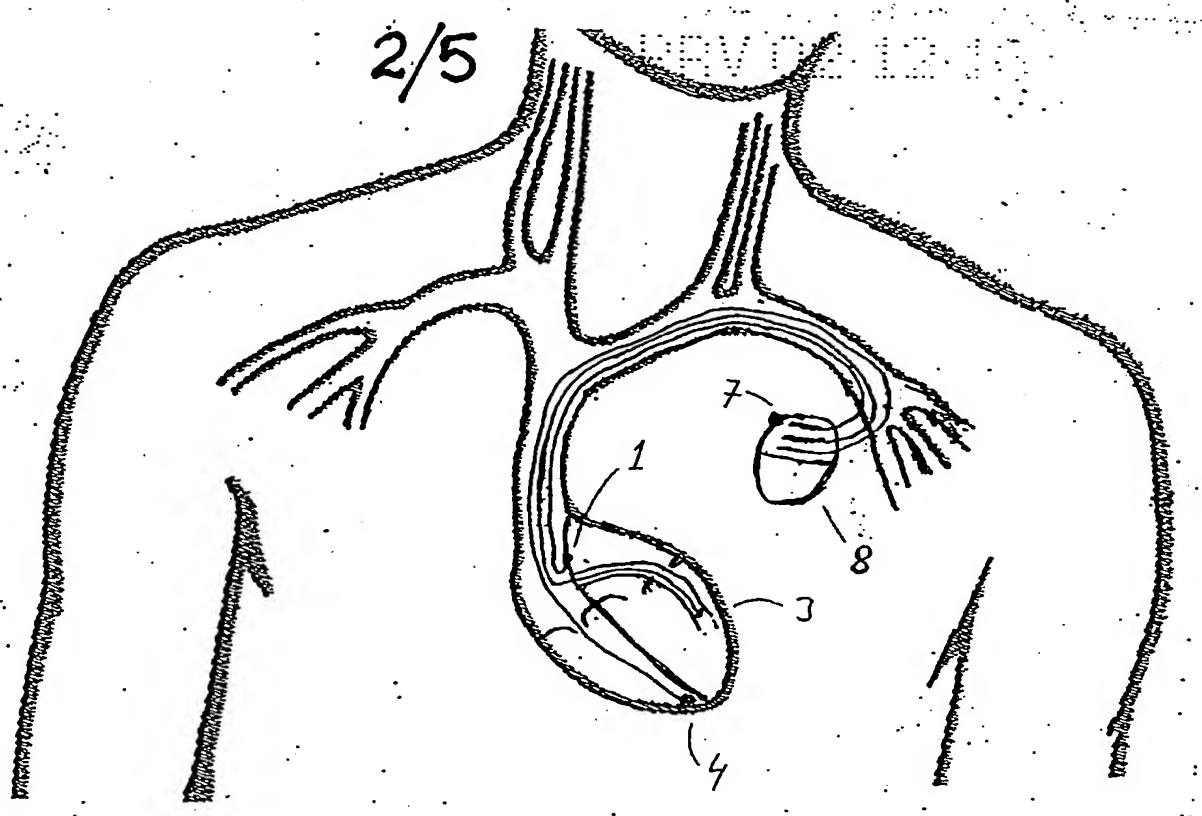

Fig 3

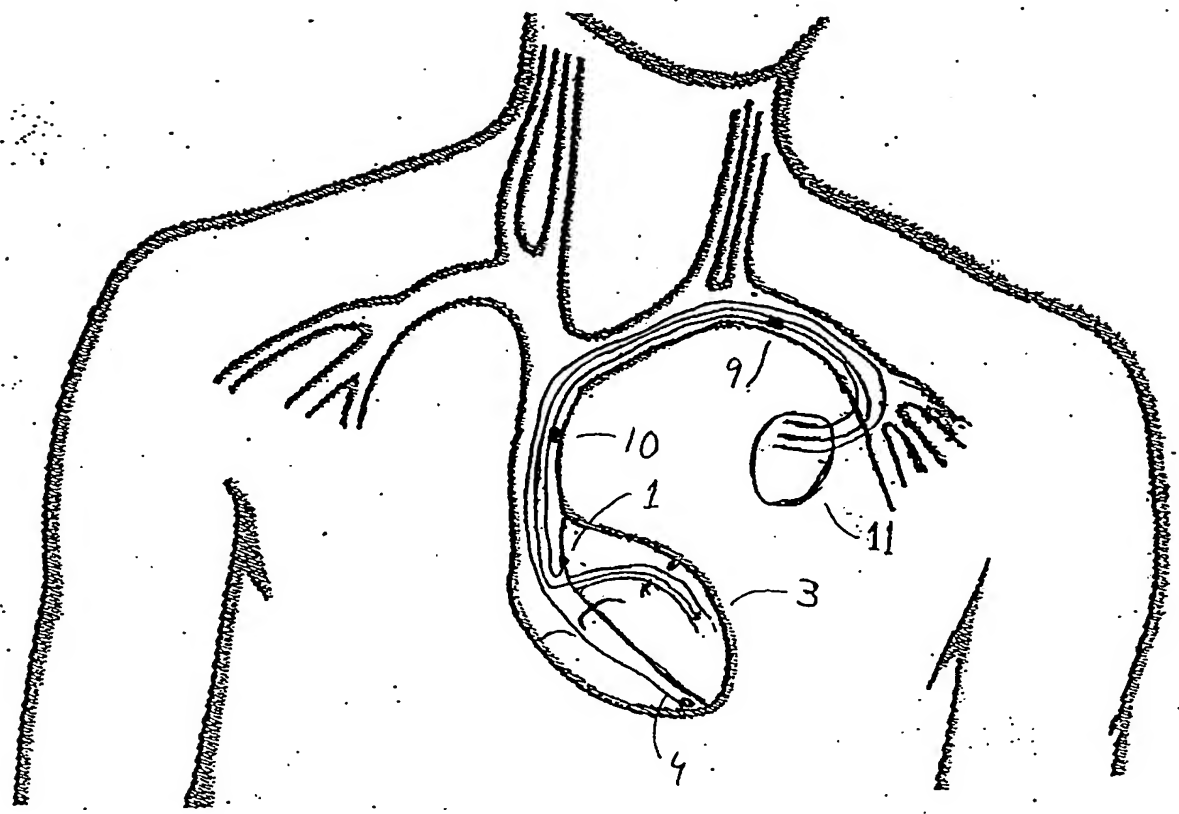

Fig 4

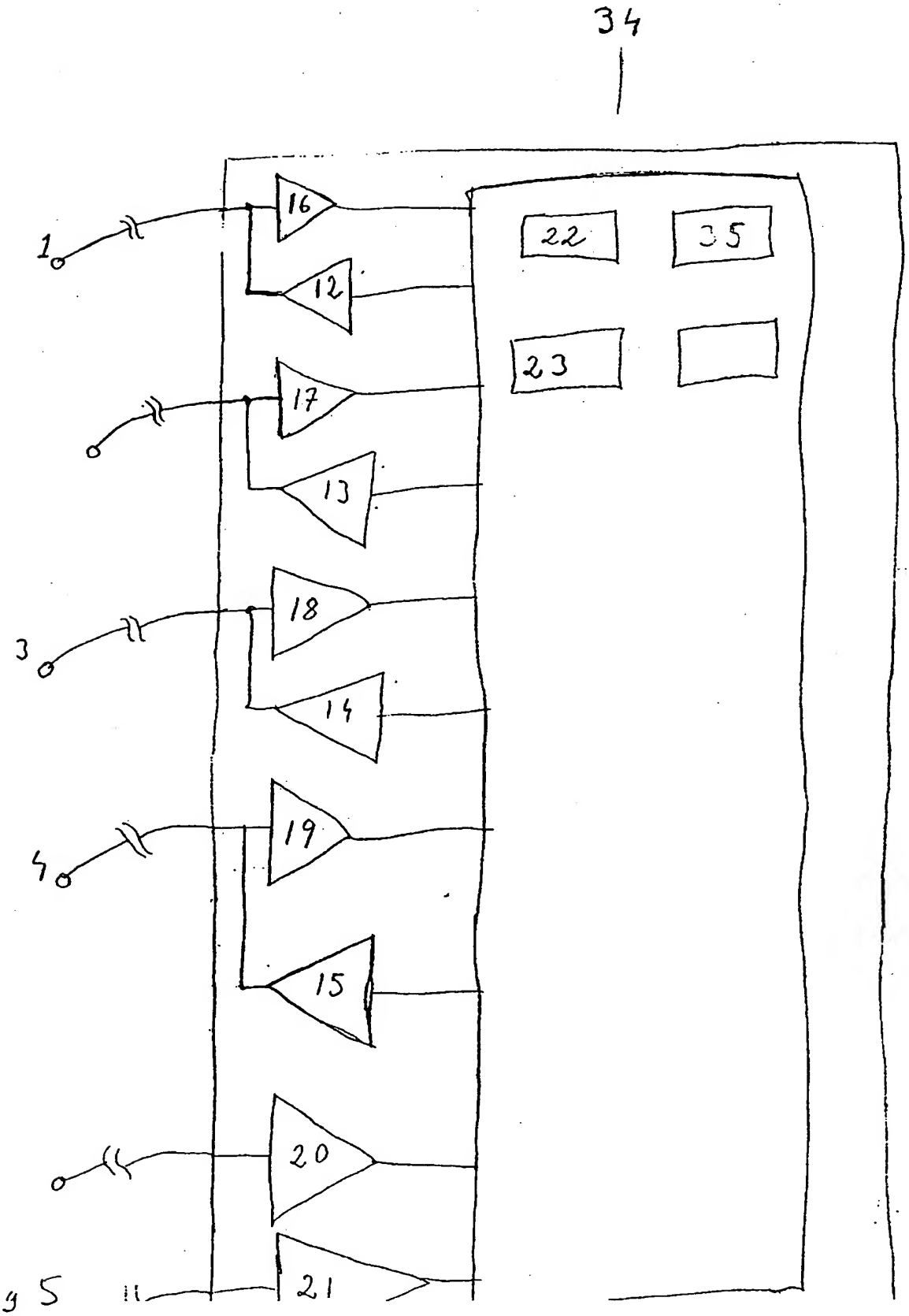

Fig 5

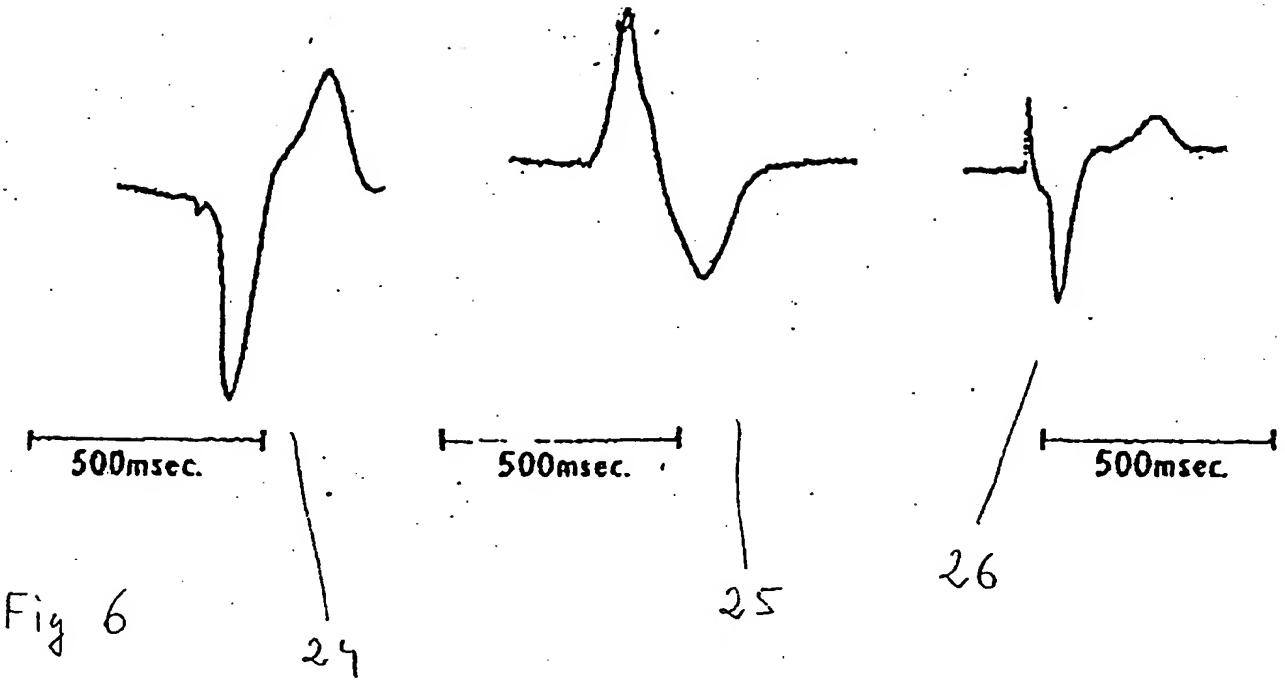

Fig 6

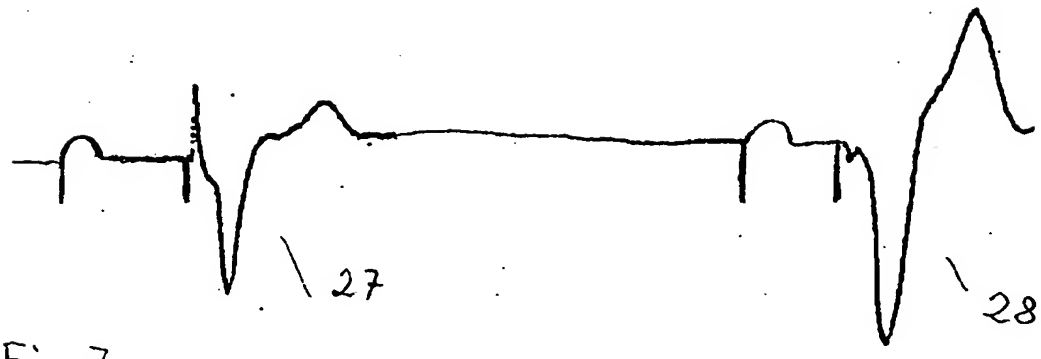

Fig 7

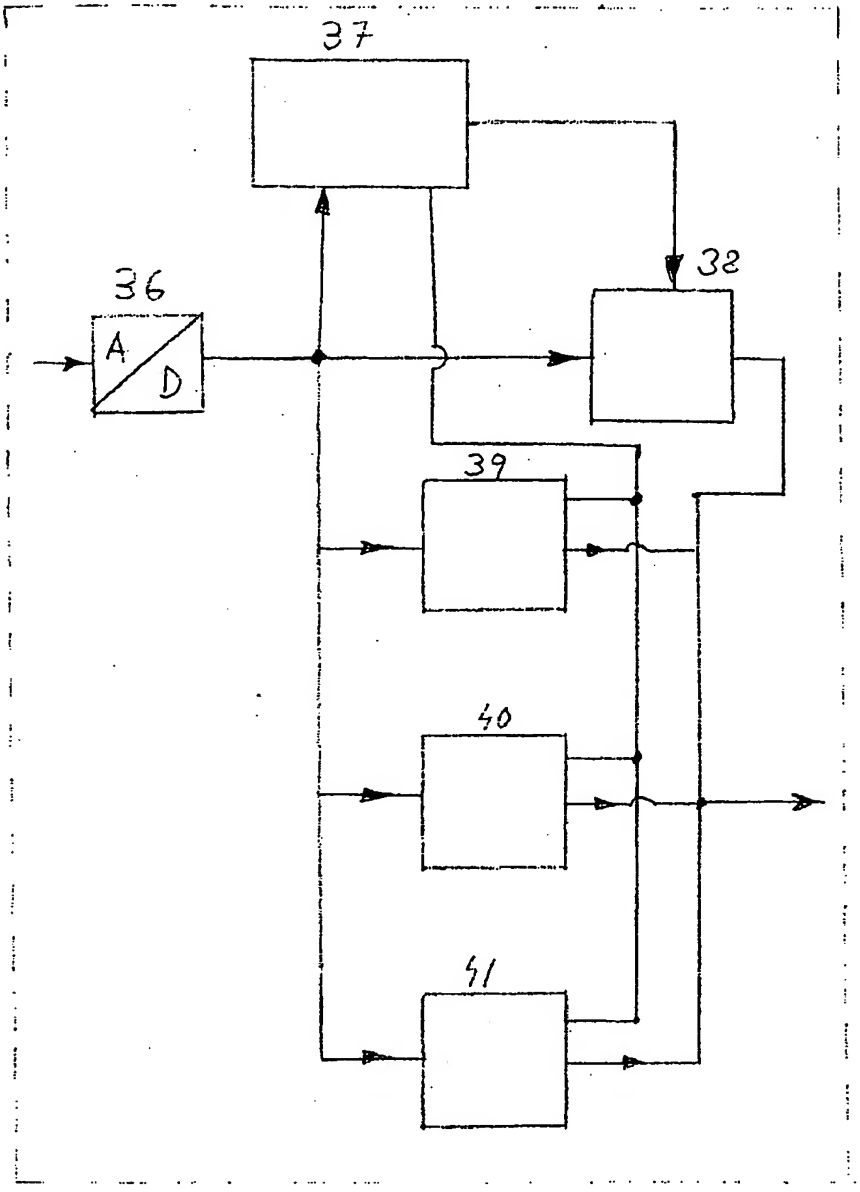

Fig 8